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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,630	01/25/2002	Ronald M. Burch	200.1079CON5	3300

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EXAMINER
GROSS, CHRISTOPHER M

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/057,630	BURCH ET AL.	
	Examiner	Art Unit	
	Christopher M. Gross	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38 and 47-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,47-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responsive to communications entered 8/2/2007. Claims 38,47-53 are pending. Claims 38,47-53 are examined herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/2/2007 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Claim Rejection(s) - 35 USC § 103

Claims 38, 47-48, 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,569,937 (Baker et al) and Swingle et al (Drugs Exptl. Clin. Res. Vol. X(8-9) (1984) pages 587-597) and/or Rabasseda (Drugs of Today Vol. 32, No. 5 (1996) pages 365-384).

Response to Arguments

Applicant argues: (i) a lack of motivation exists to combine the teachings of Baker et al with Swingle et al and/or Rabasseda; (ii) not all elements are taught; (iii) Baker et al, Swingle et al, Rabasseda each represent non-analogous art; (iv) the Examiner is using an improper "obvious to try" rationale; (v) the Examiner is improperly relying on In re Kerkoven.

Applicant's arguments have been fully considered, but they are not persuasive for the following reasons.

(i) Applicant argues, see p 4-5 (8/2/2007), that there is no motivation to substitute ibuprofen in the synergistic combination of Baker et al with another non-steroidal

antiinflammatory drug (NSAID). In particular, applicant argues that the Baker reference utilizes ibuprofen because of its enhanced analgesic effect when used with oxycodone and therefore the Baker reference teaches away from using other NSAIDs.

However, according to MPEP 2124, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The examiner submits the fact one of skill in the art *might* expect the nimesulide of Swingle et al or Rabasseda to provide additive, rather than synergistic, analgesia, when administered with oxycodone, therein representing a less preferred embodiment for Baker et al, does not constitute teaching away.

In fact, despite applicants reservations, Baker et al teach "the analgesic effect of the combination of a selected NSAID and a selected narcotic analgesic is greater than for either alone" in column 1, lines 24-25. Baker et al go on in column 1, from line 37-56 to list multiple combinations of various NSAIDs with various narcotics:

> U.S. Pat. No. 4,237,140, issued to J. R. Dudzinski on Dec. 2, 1980, describes an analgesic mixture of nalbuphine and acetaminophen. U.S. Pat. No. 4,282,215, issued to J. R. Dudzinski and W. K. Schmidt on Aug. 4, 1981,describes an analgesic mixture of nalbuphine and aspirin. Other nalbuphine analgesic combinations are described in U.S. Pat. No. 4,366,159, issued to M. R. Magruder on Dec. 28, 1982 (with narcotics); U.S. Pat. No. 4,404,210, issued to W. K. Schmidt on Sept. 13, 1983 (with ibuprofen); U.S. Pat. No. 4,407,805, issued to W. K. Schmidt on Oct. 4, 1983 (zomepirac); U.S. Pat. No. 4,402,962, issued to W. K. Schmidt on Sept. 6, 1983 (4,5-bis(4-methoxyphenyl)-2-

(trifluoromethylsulfonyl)-1H-imidazole); U.S. Pat. No. 4,407,804, issued to W. K. Schmidt on Oct. 4, 1983 (indomethacin); U.S. Pat. No. 4,404,208, issued to W. K. Schmidt on Sept. 13, 1983 (tiflamizole); U.S. Pat. No. 4,404,209, issued to W. K. Schmidt on Sept. 13, 1983 (sulindac); and U.S. Pat. No. 4,404,211, issued to W. K. Schmidt on Sept. 13, 1983 (flurbiprofen)

Notably, however, nowhere does Baker et al disparage nimesulide plus oxycodone, and according to In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004), "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...."

Applicant also argues, see p 5 (8/2/2007) last paragraph, that modifying the formulation of the Baker reference in view of Swingle et al or Rabasseda will change the mode of operation, however, as mentioned in the Office Action mailed 6/19/2007, paragraph bridging pp 4-5, both ibuprofen and nimesulide are anti-inflammatory compounds, specifically inhibitors directed against the enzyme COX2, involved in prostaglandin synthesis, facts well recognized in the prior art. Thus, both ibuprofen and nimesulide operate under the same principle. Therefore, the substitution of nimesulide for ibuprofen per Baker et al in view of Swingle et al or Rabasseda represents substituting equivalents known for the same purpose, yet another basis for obviousness according to MPEP 2144.06.

Applicant additionally argues, see p 5 (8/2/2007) last paragraph, that modifying the formulation of the Baker reference in view of Swingle et al or Rabasseda so as to provide additive effect would provide a formulation unsatisfactory for its intended use.

This is not found persuasive because the arguments of counsel cannot take the place of evidence in the record. In re Schulze,346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.") (see MPEP 2145 I.) In the instant case, Applicant's counsel argues modifying the formulation of the Baker reference in view of Swingle et al or Rabasseda will not provide beneficial analgesia, however counsel does not provide objective evidence establishing this as a fact.

(ii) Applicant argues, see pp 6-8 (8/2/2007), that Baker et al do not teach all classes of NSAIDs. Specifically, applicant interprets "This patent discloses that the analgesic effect of the combination of a selected NSAID and a selected narcotic analgesic is greater than for either alone..." [emphasis added] stated by Baker et al, as referring Sunshine et al (US Patent 4464376), which does not disclose nimsulide.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Nimesulide is provided by Swingle et al or Rabasseda.

(iii) Applicant argues, see p 8-10 (8/2/2007), that Swingle et al or Rabasseda do not teach that nimulsilide is equally efficacious with less side effects than ibuprofen, per the Office Action mailed 9/29/2005.

In particular, applicant argues, see p 8 last paragraph through p 10 first paragraph (8/2/2007), that Swingle et al or Rabasseda do not compare ibuprofen with nimulsilide, however applicant's attention is respectfully invited to figure 10 of Swingle et al, which compare the ulcerogenic activity of ibuprofen with nimesulide and table 1 and figure 4 of Rabasseda which compares the COX2 selectivity of nimesulide vs. ibuprofen.

Applicant further argues, see p 9 last paragraph (8/2/2007) that Swingle et al and Rabasseda do not definitively conclude that nabumetone has less side effects than ibupfofen with regard to skin side reactions. It is not clear to the Examiner how a clinical data concerning nabumetone is related to the nimulsilide of the present application. Applicant also refers to the Eversmeyer reference of Exhibit A, but no such exhibit has been provided.

Assuming arguendo, that ibuprofen does indeed have less side effects related to the skin than nimesulide, which may affect a particular subpopulation, it the Examiner's position that gastrointestional tolerance still represents another subpopulation that would benefit from nimulsilde, thus motivation remains in substituting the nimesulide of Swingle et al or Rabasseda for the ibuprofen of Baker et al.

(iv) Applicant argues, see p 10-15 that the Examiner is relying on an improper "obvious to try" rationale because Baker et al (and Sunshine et al) do not explicitly mention nimesulide.

In this regard, the Supreme Court has stated in KSR Int'l Co. v. Teleflex Inc No. 04-1350 (S.Ct. Apr 30, 2007) /550 U.S._____, 82 USPQ2d 1385 (2007) that a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious over section 103. See especially *KSR* U.S._____, 82 USPQ2d at 1397 (2007). Emphasis added.

(v) Applicant argues, see p 15-16 that the Examiner is improperly relying on In re Kerkoven because a combination of the Baker analgesic composition with that of Swingle et al or Rabasseda would result in a formulation of nimulsilide, ibuprofen and an opioid narcotic.

The Examiner agrees said formulation would not read on the presently claimed invention, however in view of the other outstanding issues discussed above, the rejection is maintained.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (US patent 4,569,937), Swingle et al. and/or Rabasseda as applied to claims 38, 47-48, and 50-53 above, and further in view of Oshlack et al. US Pat. No. 5,472,712 (12/95) or Oshlack et al. US Pat. No. 6,294,195 (9/01: effectively filed 10/93 or earlier).

Response to Arguments

Applicant does not offer further arguments regarding the above obviousness rejections beyond what was set forth with regard to the 35 U.S.C. § 103 rejection. To the extent that Applicant is merely repeating their previous argument, the Examiner contends that those issues were adequately addressed in the above sections, which are incorporated in their entireties herein by reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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cg

/Jon D. Epperson/
Primary Examiner, AU 1639